Atty Dkt 8325-1004
PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

WANG and PABO

Serial No.: 09/636,243

Group Art Unit: 1639

Filing Date: August 10, 2000

Examiner: T. Wessendorf

Title: DIMERIZING PEPTIDES

APPEAL BRIEF TRANSMITTAL

MAIL STOP Appeal Brief-Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Further to the Notice of Appeal filed July 8, 2003, transmitted herewith for filing in the above-identified patent application is an Appeal Brief in triplicate. A check for $320 to cover the fee is also enclosed.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648.

Respectfully submitted,

Date: Aug 5, 2003

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USSN 09/636,243
8325-1004
M4-US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Examiner: T. Wessendorf
WANG and PABO	Group Art Unit: 1639
For: **DIMERIZING PEPTIDES**	Confirmation No.: 6438
Serial No.: 09/636,243	
Filed: August 10, 2000	
Atty. Docket No.: 8325-1004 (M4-US1)	

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BRIEF ON APPEAL

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BRIEF ON APPEAL

Mail Stop Appeal Brief
Commissioner for Patents
Alexandria, VA 22313

Sir:

INTRODUCTION

Appellants submit in triplicate their brief on appeal in accordance with 37 C.F.R. §1.192. All claims were finally rejected under 35 U.S.C. § 112, first and second paragraphs, as well as under 35 U.S.C. § 102. The specification was also objected to as allegedly confusing and containing new drawings. A Notice of Appeal was filed July 8, 2003, making a Brief on Appeal due on or before September 8, 2003. Accordingly, this Brief is timely filed. Appellants respectfully request that the decision of the Examiner be reversed.

I. REAL PARTIES IN INTEREST

The Massachusetts Institute of Technology, the assignee of record of the above-referenced patent application; and Sangamo BioSciences, Inc., the exclusive licensee of the above-referenced patent application, are the real parties in interest in this matter.

II. RELATED APPEALS AND INTERFERENCES

Appellants are not aware of any related appeals or interferences.

III. STATUS OF THE CLAIMS

Claims 5, 6 and 20 are currently pending in the above-referenced case (hereinafter "the application"). The application was originally filed on August 10, 2000 with claims 1 to 19. A substitute specification and preliminary amendment were filed on January 30, 2001. The Office approved the substitute specification and, subsequent to approval, a Restriction Requirement was mailed on July 25, 2002. In a Response to Restriction Requirement, dated August 26, 2002, claims 5 and 6 were elected with traverse. In an amendment filed on December 19, 2002, claims 5 and 6 were amended and claim 20 was added. Accordingly, claims 5, 6 and 20 are pending as shown in Appendix A. All pending claims remain rejected under 35 U.S.C. § 112, first and second paragraphs and under 35 U.S.C. § 102.

IV. STATUS OF THE AMENDMENTS

In response to the Examiner's Final Office Action mailed April 8, 2003, Appellants filed an Amendment After Final on May 7, 2003, amending the specification and claims 5, 6 and 20. Appellants also addressed an objection to the drawings. An Advisory Action was mailed on June

4, 2003, indicating that amendments to the claims would not be entered. The amendments to the specification and clarification of the drawings were not addressed in the Advisory Action. Thus, all claims remained rejected for the reasons set forth in the Final Office Action. In addition, since the objections to the specification and drawings were not withdrawn by the Examiner, Appellants conclude that they are still outstanding.

V. SUMMARY OF THE CLAIMS

Appellants' claims are drawn generally to protein complexes made up of two or more fusion proteins (page 3, lines 26-29). In particular, each fusion protein of the complex comprises a zinc finger protein and a dimerizing peptide (page 3, lines 26-32 and page 11, lines 15-22). The fusion proteins (each containing a zinc finger protein and a dimerizing peptide) are joined to one another by specific binding between their own dimerizing peptide linkers (page 3, lines 29-30). Furthermore, the dimerizing peptide linkers are non-naturally occurring peptides (page 3, lines 30-31). The peptide linkers of each fusion (zinc finger-peptide fusion) may have the same amino acid sequence (page 3, lines 31-32). Similarly, the zinc finger protein of each fusion protein may also have the same amino acid sequences (page 13, lines 25-27).

Thus, the present claims provide protein complexes that contain two or more zinc finger-dimerizing peptide fusion proteins that are useful for mediating association to target sequences (e.g., DNA sequences) and which may afford greater specificity and/or affinity binding of the zinc finger proteins to the target (page 11, lines 12-14).

VI. ISSUES ON APPEAL

1. Whether the drawings as described in the substitute specification were contained in the originally filed specification.

2. Whether the headings in the substitute specification are unduly confusing.

3. Whether the specification provides adequate written description for pending claims 5, 6 and 20 under 35 U.S.C. § 112, first paragraph.

4. Whether pending claim 5 is sufficiently definite under 35 U.S.C. § 112, second paragraph.

5. Whether pending claim 5 is anticipated by Kim et al. (1998) *Proc. Nat'l Acad. Sci. USA* 95:2812-2817 under 35 U.S.C. § 102(b).

6. Whether pending claims 5, 6 and 20 are anticipated by Pavletich et al. (1991) *Science* 252:809-817 under 35 U.S.C. § 102(b).

VII. GROUPING OF CLAIMS

Claims 5, 6 and 20 are separately patentable, enabled and described by the application as filed. Therefore, these claims are divided into 3 separate groups:

(1) Claim 5: Independent claim 5 is directed to a zinc finger complex comprising two or more fusion proteins. Each fusion protein comprises a zinc finger protein and a non-naturally occurring dimerizing peptide linker. Furthermore, the fusion proteins are joined together by specific binding of the peptide linkers.

(2) Claim 6: Claim 6 is directed to the zinc finger complex of claim 5 and further specifies that the peptide linker of each fusion protein is the same peptide.

(3) Claim 20: Claim 20 is directed to the zinc finger complex of claim 5 and further specifies that the zinc finger protein of each fusion protein has the same sequence.

VIII. ARGUMENTS

1. No drawings were added in the Substitute Specification

In the Final Office Action, the Examiner repeated the assertion that the substitute specification contained additional drawings. (Final Office Action, page 2). Specifically, the Examiner has repeatedly stated that the original specification contained only two Figures and that the substitute specification somehow added "new" drawings. (Final Office Action, page 2). Appellants had again addressed this issue in their Response After Final, but the Advisory Action did not indicate whether Appellants' statements had clarified the situation for the Examiner. Accordingly, Appellants assume that the Examiner's position remains that the substitute specification contained additional drawings.

Appellants submit that, contrary to the Examiner's assertion, there is a perfect correspondence between the drawings in the application filed August 10, 2000 and those presented in the substitute specification. Indeed, the application filed August 10, 2000 contained a total of 9 drawings -- 2 Figures described in the "Brief Description of the Figures;" 4 drawings embedded in Example 1 (labeled as Figure 1-4 in Example 1 of the as-filed application); and 3 drawings embedded in Example 2 (labeled as Figures 1-3 in Example 2 of the as-filed application). As detailed in the preliminary amendment filed with the substitute specification, the labels of the Figures embedded within Examples 1 and 2 of the as-filed specification were corrected and the Brief Description of the Drawings amended as follows:

Reference No. in App filed 8.10.00	**Reference No. in Substitute Spec**
Figure 1 in Brief Description	Figure 1 in Brief Description
Figure 2 in Brief Description	Figure 2 in Brief Description
Figure 1, panels A-C of Example 1	Figure 3, panels A-C in Brief Description
Figure 2, panels A-B of Example 1	Figure 4, panels A-B in Brief Description
Figure 3 of Example 1	Figure 5 in Brief Description
Figure 4 of Example 1	Figure 6 in Brief Description
Figure 1 of Example 2	Figure 8 in Brief Description
Figure 2 of Example 2	Figure 9 in Brief Description
Figure 3 of Example 2	Figure 7 in Brief Description

Thus, the application filed August 10, 2000 and substitute specification both contain exactly nine Figures and, moreover, the substance and the descriptions of these drawings are identical. Accordingly, Appellants submit that this objection is in error in and should be withdrawn.

2. The Headings in the Specification are not confusing

The Final Office Action also reiterated the objection to allegedly "confusing" headings in the specification. (Final Office Action, page 4). In particular, the manuscript-type material in Examples 1 and 2 was alleged to be confusing.

In an Amendment, mailed December 19, 2002, Appellants eliminated the duplicative occurrences of the word "abstract" in the Examples and, in an Amendment After Final, mailed May 7, 2003, Appellants offered to amend the specification to delete further material. (See, page 5 of the Amendment After Final, filed on May 7, 2003). Since the Examiner did not address the objection to the specification in the Advisory Action, it is assumed that the Examiner stands by her assertion that:

> ...elimination of the heading "abstract" does not remove the confusion as to the presence of said abstract in the Examples. In patent applications, working examples provided in the specification should admit an illustration of the invention and should not contain a disclosure of the general background of the prior art or an abstract. Thus, the incorporation of the entire manuscripts in the Examples is confusing. Cf. with the provisional application of 60/148,422, filed on 8/11/99, which did not include applicants' own work, i.e., the entire manuscripts. (Final Office Action, mailed April 8, 2003, page 4).

Contrary to the Examiner's assertions, the Examples Section of an application may contain background disclosure and citations to any number of references. An applicant is free to include any information they deem appropriate in the detailed description of their specification. (See, also, Office Action, mailed September 25, 2002, where the Office noted, "the Examples need not contain a disclosure of the general background...," emphasis added as compared to the objection as stated in the Final Office Action that the Examples should not contain background

information). Therefore, the inclusion of so-called "background" information in the Examples Section is neither improper nor confusing.

The Examiner also errs in stating that the incorporation of entire manuscripts in the Examples is confusing. Manuscripts are often incorporated into patent applications and, indeed, there are numerous examples of issued patents in which manuscripts have been incorporated in the same manner as in Appellants' specification. Specifically, there is nothing improper about submitting "manuscript-type material" as Examples. Even though not required, Appellants again note that they have removed all duplicative headings and, as such, there is no confusion regarding manuscript-type material.

Finally, the Examiner improperly asserts that a utility application must be identical to the provisional application from which priority is claimed. Thus, it appears that the Examiner is attempting to limit Appellants to only those Figures that appeared in the provisional application. Appellants are not aware of any prohibition against adding additional disclosure in a utility application that claims the benefit of a provisional application. By somehow invoking an "identity" test, the Examiner in the pending case has elevated the form of the applications over their substance. This is entirely improper.

Therefore, the objections to the specification are improper and Appellants request that they be removed.

3. The Specification Describes the Claims on Appeal

The Examiner has continued to allege that the specification does not provide adequate written description for pending claims 5, 6 and 20. The Examiner's position remains that:

> The as-filed specification does not contain a description of a zinc finger complex comprising more than two fusion proteins linked via the non-naturally occurring peptide sequences. There is no description in the specification as to the maximum limit of the term "more" than two fusion proteins. More importantly, there is no description as to whether the linking of the two linkers result in a stable fusion protein complex containing more than two zinc finger fusions. This is confusing since the Examples do not describe any linking of non-naturally occurring peptide

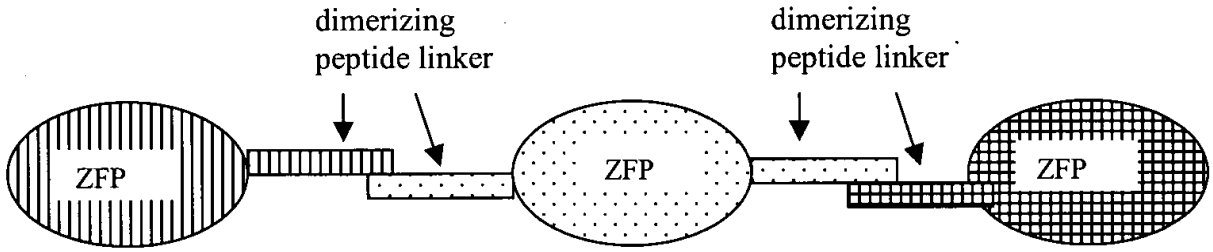
> linkers to fuse more than two zinc finger proteins of similar sequences. Furthermore, the as-filed specification does not describe a zinc finger protein having the same sequence. (Final Office Action, pages 5-6).

Appellants submit that there is ample description in the specification regarding stable linkage of more than two fusion proteins and, as such, the written description requirement of 35 U.S.C. § 112, first paragraph has been satisfied.

The fundamental factual inquiry in written description is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117. Determining whether the written description requirement is satisfied is a question of fact and the burden is on the Examiner to provide evidence as to why a skilled artisan would not have recognized that the applicant was in possession of claimed invention at the time of filing. *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991); *In re Wertheim,* 191 USPQ 90 (CCPA 1976). It is not necessary that the application describe the claimed invention *in ipsis verba.* Rather, all that is required is that the specification reasonably conveys possession of the invention. *See, e.g., In re Lukach,* 169 USPQ 795, 796 (CCPA 1971). Finally, determining whether the written description requirement is satisfied requires reading the disclosure in light of the knowledge possessed by the skilled artisan at the time of filing, for example as established by reference to patents and publications available to the public prior to the filing date of the application. *See, e.g., In re Lange,* 209 USPQ 288 (CCPA 1981).

Because any written description inquiry must begin with claim construction, it is important to note at the outset that the claims on appeal are drawn to complexes that can include multiple zinc finger proteins linked via specific binding of two dimerizing peptide linkers (one or more linkers associated with each fusion protein). Furthermore, each zinc finger protein of the fusion protein components itself contains a plurality of zinc finger components, *i.e.,* is a multi-finger (polydactyl) zinc finger protein. Thus, the claims on appeal do not, as asserted by the Examiner, encompass any and all fusion proteins.

The application as filed fully describes the complexes of claims 5, 6 and 20. The application describes, in detail, how multiple polydactyl zinc finger proteins are linked using non-naturally occurring dimerizing peptides. (*See, e.g.*, page 11, lines 8-14; page 11, lines 20-22; and Examples 1 and 2). Thus the claimed complexes can be schematically depicted as follows and clearly can include two or more fusion proteins:



Further, the application clearly describes how the complexes can include two or more of such zinc finger proteins and how the proteins can be the same or different:

> Dimerizing peptides selected by phage display are useful for mediating multimerization of zinc finger proteins or other types of protein. A typical application of such peptides is to mediate association of two different zinc finger proteins that have proximate target segments within a target sequence. (See, page 12, lines 20-23)...
>
> Different zinc finger proteins can be used preassociated or can be used separately in which case they associate in situ. Often zinc finger proteins linked to dimerizing peptides of the invention remain dissociated in solution, and dimerized only on binding to DNA. Such is advantageous in promoting dimerization between two different zinc finger proteins linked to the dimerizing peptides relative to homodimerization of the two copies of the same zinc finger protein. For example, if a target sequence contains adjacent sites for two different zinc finger proteins, both zinc finger proteins can bind simultaneously to the target sequence, and then dimerize with each other mediated by the linked dimerizing peptide. By contrast, two copies of the same zinc finger cannot usually bind adjacent to each other on the same target sequence (unless by coincidence the target contains an inverted repeat of the target site for that zinc finger). (See, page 13, lines 22-34).

Thus, there is clear description in the application as filed regarding all the claimed elements. Accordingly, in view of Appellants' disclosure and state of the art, it would have been

plain to the skilled artisan that Appellants were in possession of the claimed subject matter at the time the application was filed.

4. Claim 5 is definite

Claim 5 was rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. (Final Office Action, pages 6-7). In particular, the term "two or more" was alleged to be unclear as it relates to fusion peptides. (Final Office Action, page 6). In addition, the metes and bounds of the term "non naturally occurring amino acids" are alleged to be not clearly set forth. (Final Office Action, page 7).

Applicants note at the outset that the claims do not recite "non naturally occurring amino acids" as set forth in the Final Office Action. (Final Office Action, page 7). Rather, the claims define the peptide linkers, in part, by the fact that they are non naturally occurring peptides. For the reasons of record and those reiterated herein, the metes and bounds of the term "non naturally occurring peptide" is clearly set forth in the specification as filed.

The definiteness requirement of 35 U.S.C. § 112, second paragraph is satisfied if it is clear to the skilled artisan what is meant by a particular claim term. *See, e.g., In re Marosi,* 218 USPQ 289 (Fed. Cir. 1983). Further, the definiteness and clarity of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular disclosure; (2) the teachings of the art; and (3) the claim interpretation that would be given by one possessing ordinary skill in the pertinent art at the time the invention was made. *See, e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc.,* 220 USPQ 202 (Fed. Cir. 1983). In other words, the terms at issue must be read in context of the application and field of endeavor.

Appellants submit that the term "two or more" as it relates to fusion proteins clearly refers to a complex containing multiple (at least two) fusion proteins. Not only is the term used in a conventional sense that would be readily understood by the skilled artisan, the application as filed makes numerous references to multiple zinc finger-containing fusion proteins joined in a complex. *See, e.g.,* page 12, lines 20-23; page 11, lines 8-14; and the Abstract of the application.

An exemplary complex containing three fusion proteins is shown schematically on page 9 of this Appeal Brief and illustrates how one of skill in the art would readily understand what a complex having two or more fusion proteins would look like.

With regard to the term "non-naturally occurring," the paragraph beginning on line 3 of page 8 of the application, clearly defines this term to include only those "sequences not found in nature." Additional metes and bounds are also set forth in this paragraph:

> Conversely, the term nonnaturally-occurring is used to describe objects and sequences not found in nature. Preferred nonnaturally occurring sequences show no significant sequence identity, e.g., less than 50% (amino acid or nucleotide) with natural sequences, in distinction from induced mutations of natural sequences. Typically, nonnaturally occurring sequences do not contain a contiguous segment of at least half their length with a natural protein. Some nonnaturally occurring peptides fold in conformations distinct from natural peptides. Some nonnaturally occurring sequences are selected from random peptide libraries.

In other words, the specification plainly defines what is included or excluded from by the recitation "non-naturally occurring" as naturally occurring linker sequences are clearly excluded from the scope of the pending claims.

Thus, when properly read in light of the specification, claim 5 reasonably apprises those skilled in the art as to the metes and bounds of the claimed subject matter and is more than sufficiently precise. Accordingly, withdrawal of this rejection is respectfully requested.

5. Anticipation has not been established

In the Final Office Action, the Examiner rejected claim 5 as allegedly anticipated by Kim et al. (1998) *Proc. Nat'l Acad. Sci. USA* 95:2812-2817 (hereinafter "Kim") and claims 5, 6 and 20 as allegedly anticipated by Appellants' disclosure of Pavletich et al. (1991) *Science* 252:809-817 (hereinafter "Pavletich"). The Examiner maintained that Kim's disclosure of a "longer" linker between zinc finger proteins met "the instantly claimed zinc finger complex." (See, Final Office Action, page 8). Similarly, Appellants' disclosure at page 41, line 32 to page 42, line 5, referring to Pavletich, was cited by the Examiner as evidence that the "prior art disclosed by

applicants fully meets the claimed zinc finger complex wherein each of the zinc finger, Zif (1 and 2) are joined each to a linker." (Final Office Action, page 8).

In order to establish that a single reference anticipates the claims, the Examiner bears the burden of showing that each and every element of the claims is described within the four corners of the reference. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick,* 221 USPQ 481, 485-86 (Fed. Cir. 1984). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Foundation v. Genentech, Inc.,* 18 USPQ2d 1896 (Fed. Cir. 1991).

It is also well established that not only must every element be identically shown in a single reference, but, in addition, that these elements must be arranged as in the claim under review. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick,* 221 USPQ 481, 485-86 (Fed. Cir. 1984). "The [allegedly anticipating] patent discloses an entirely different device, composed of parts distinct from those of the claimed invention and operating in a different way to process different material differently." *Id.* Thus, the claims cannot be viewed as "mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning." *Id.*

In the pending case, the Examiner has not met this burden. Anticipation of the pending claims by Kim or Pavletich has not been (and indeed cannot be) established.

(a) The Examiner has not established that Kim or Pavletich disclose each and every element of the claimed protein complexes

The Examiner has improperly modified the teachings of Kim and Pavletich in imposing a rejection of claims 5, 6 and 20 based on § 102(b). Neither reference describes each and every element of these claims and neither arranges the claimed elements in the novel relationships set forth in the claims.

In the present case, claim 5, the single independent claim from which claims 6 and 20 depend, is drawn to a complex of two or more fusion proteins. Each fusion protein includes a

zinc finger protein and a non-naturally occurring peptide linker. Specific binding of two peptide linkers to one another joins the individual fusion proteins together. Therefore, any reference cited pursuant § 102(b) must disclose to a person of ordinary skill in the field of protein biology at least the following elements: (1) a complex containing two or more fusions proteins; (2) each fusion protein of the complex comprising a zinc finger protein and a peptide linker; (3) where the fusion proteins are joined together via specific binding of their linkers; and (4) that the peptide linkers are non-naturally occurring peptides. Kim and Pavletich fail to disclose each and every one of these elements.

Kim describes a single fusion protein, namely a fusion of Zif268 with an NRE polypeptide that specifically recognizes a nuclear hormone response element. Kim does not in any way teach or suggest complexes of two fusion proteins joined by linkers and in which each fusion protein contains a zinc finger protein and a peptide linker. There is, therefore, no teaching or suggestion in Kim which would lead a skilled artisan to use dimerizing peptides to link zinc finger-containing fusion proteins and the subject matter of claim 5 cannot be anticipated by Kim.

Turning to the second rejection under 35 U.S.C. § 102(b), Appellants note that the Examiner has erred in citing the application itself as the allegedly anticipatory reference. (See, page 8 of Final Office Action). An anticipation rejection cannot be based on an applicant's own disclosure, but must instead be based on what is disclosed in a proper § 102 reference. Thus, the rejection of claims 5, 6 and 20 based on "applicants' disclosure referring to Pavletich" is improper.

In any event, Pavletich, like Kim, does not describe each and every element of claims 5, 6 and 20. In particular, Pavletich fails to suggest a complex in which fusion proteins are linked via two (dimerizing) peptide linkers. Rather, Pavletich discloses the crystal structure of Zif268 bound to DNA. (*See, also,* page 41, line 32 of the specification noting that Zif268 as disclosed in Pavletich is the starting material for additional experiments described in the application that then resulted in the claimed molecules).

Thus, Kim and Pavletich contain absolutely no disclosure regarding linking a plurality of zinc finger proteins together where each ZFP contains its own dimerizing peptide linker and neither references provides any suggestion to do so. Accordingly, because Kim and Pavletich fail to describe, demonstrate or suggest the molecules as claimed, Appellants submit that withdrawal of this rejection is in order.

6. Additional Arguments Regarding Separately Grouped Claims

Each one of the preceding arguments is applicable to all of the separately grouped claims, *i.e.*, to each claim individually. For the sake of brevity, the arguments have been set out primarily as to independent claim 5. Claims 6 and 20 contain all the elements of claim 5 and are, therefore, described, definite and patentable over the cited references for the reasons discussed in detail above. The dependent claims are also further limited in ways that are neither described nor suggested by the cited references, namely by further defining the elements of the claimed fusion proteins. The Examiner has not adequately explained why these claims are considered unpatentable over the cited references.

CONCLUSION

For the reasons stated above, Appellants respectfully submit that the pending claims are patentable over the art cited by the Examiner and, in addition, are described and sufficiently definite. Accordingly, Appellants request that the objections to the specification and the rejections of the claims on appeal be reversed, and that the application be remanded to the Examiner so that the appealed claims can proceed to allowance.

Respectfully submitted,

Date: Aug 5, 2003

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CLAIMS ON APPEAL

5. (previously amended): A zinc finger complex, comprising two or more fusion proteins, each fusion protein comprising a zinc finger protein and a peptide linker, wherein the fusion proteins are joined to each other by specific binding of the peptide linkers, and wherein the peptide linkers are non-naturally occurring peptides.

6. (previously amended): The zinc finger complex of claim 5, wherein the peptide linker of each fusion protein is the same.

20. (previously added): The zinc finger complex of claim 5, wherein the zinc finger protein of each fusion protein has the same sequence.